

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

No. C 09-04124 CW

STEPHEN WENDELL AND LISA WENDELL, for  
themselves and as successors in  
interest to MAXX WENDELL, deceased,

ORDER GRANTING IN  
PART AND DENYING IN  
PART ABBOTT  
LABORATORIES' MOTION  
TO DISMISS

Plaintiffs,

v.

JOHNSON & JOHNSON, et al.,

Defendants.

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This is a products liability action concerning three prescription drugs, Remicade, Humira and Purinethol. Defendant Abbott Laboratories (Abbott Labs), the manufacturer of Humira, moves to dismiss all claims alleged against it. Plaintiffs oppose the motion. The matter was taken under submission on the papers. Having considered all of the parties' papers, the Court grants Abbott Labs' motion in part and denies it in part .

BACKGROUND<sup>1</sup>

Plaintiffs allege that Defendants' products, used either alone or in combination, resulted in Maxx Wendell's development of hepatosplenic T-Cell lymphoma in 2007. Plaintiffs' claims against Abbott Labs concern the company's failure to warn adequately of lymphoma risks associated with an off-label use of Humira.

In 1998, at the age of twelve, Maxx Wendell was diagnosed with

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<sup>1</sup>The following facts are alleged in the complaint.

1 inflammatory bowel disease and ulcerative colitis. Initially he  
2 was treated with a course of mercaptopurine (6-MP) and prednisone,  
3 a steroid. Compl. ¶ 59. Mercaptopurine, also sold under the brand  
4 name Purinethol,<sup>2</sup> is a "purine analog which interfered with nucleic  
5 acid biosynthesis and has been found to be active against human  
6 leukemias." Id. at ¶ 55. The only FDA-approved use of  
7 mercaptopurine is for the "remission induction and maintenance  
8 therapy of acute lymphatic leukemia." Id.

9 In May, 2002, Wendell's physicians recommended adding Remicade  
10 to his treatment regimen<sup>3</sup> with a course of steroid weaning. In  
11 June or July, 2002, Wendell received his first dose of Remicade.  
12 Remicade is a TNF- $\alpha$  inhibitor, which is designed to suppress the  
13 immune system in ways that can reduce the symptoms of autoimmune  
14 disorders, such as Crohn's disease and rheumatoid arthritis. Id.  
15 at ¶ 44. In November, 2006, Wendell's doctors replaced his intake  
16 of Remicade with Humira. Humira is also a TNF- $\alpha$  inhibitor with  
17 anti-inflammatory effects that provides relief for many symptoms  
18 affecting rheumatoid arthritis. Id. at ¶ 50. Humira is designed  
19 and manufactured by Abbott Labs. Id. at ¶ 21. He received at  
20 least five doses of Humira between November, 2006 and June, 2007.  
21 Id. at ¶ 63.

22 In July, 2007, doctors diagnosed Wendell with hepatosplenic T-  
23 cell lymphoma. Id. at ¶ 64. Despite aggressive chemotherapy and  
24 other treatments, Wendell died on December 19, 2007. Id. at ¶ 65.

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25 <sup>2</sup>Purinethol is manufactured by Defendants Smithkline Beecham,  
26 Teva Pharmaceuticals USA and Gate Pharmaceuticals. Compl. ¶¶ 22-  
27 24.

28 <sup>3</sup>Remicade is manufactured by Defendants Johnson & Johnson and  
Centocor, Inc. Compl. ¶ 19.

1 Plaintiffs allege that, following FDA approval of "Remicade in  
2 1998 for treatment of rheumatoid arthritis and Crohn's disease in  
3 adults, it became common practice to prescribe mercaptopurine in  
4 combination concomitantly with TNF-blockers like Remicade or Humira  
5 in the treatment of autoimmune disorders." Id. at ¶ 57.

6 Plaintiffs allege that such use, "which was not approved by the FDA  
7 -- was not only known to Defendants herein but encouraged and/or  
8 promoted and/or fostered and/or otherwise enabled by Defendants  
9 herein and each of them without adequate testing on the safety  
10 and/or efficacy of such combination use or in the pediatric or  
11 young adult populations." Id.

12 Plaintiffs assert ten causes of action against all Defendants:  
13 (1) fraud and deceit, (2) negligence, recklessness and gross  
14 negligence, (3) negligent misrepresentation, (4) negligence,  
15 (5) negligence per se, (6) strict liability, (7) breach of express  
16 warranty, (8) breach of implied warranty, (9) violation of Business  
17 and Professions Code Section 17200, et seq. and (10) wrongful  
18 death. Plaintiffs filed the complaint on June 2, 2009 in the  
19 Superior Court of California for San Francisco County. Plaintiffs  
20 served Abbott Labs on August 6, 2009 and on September 4, 2009,  
21 Abbott Labs removed the case to federal court. Plaintiffs have not  
22 challenged the removal. On September 27, 2009, Abbott Labs filed  
23 the instant motion to dismiss.

#### 24 LEGAL STANDARD

25 A complaint must contain a "short and plain statement of the  
26 claim showing that the pleader is entitled to relief." Fed. R.  
27 Civ. P. 8(a). When considering a motion to dismiss under Rule  
28 12(b)(6) for failure to state a claim, dismissal is appropriate

1 only when the complaint does not give the defendant fair notice of  
2 a legally cognizable claim and the grounds on which it rests. Bell  
3 Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). In  
4 considering whether the complaint is sufficient to state a claim,  
5 the court will take all material allegations as true and construe  
6 them in the light most favorable to the plaintiff. NL Indus., Inc.  
7 v. Kaplan, 792 F.2d 896, 898 (9th Cir. 1986). However, this  
8 principle is inapplicable to legal conclusions; "threadbare  
9 recitals of the elements of a cause of action, supported by mere  
10 conclusory statements," are not taken as true. Ashcroft v. Iqbal,  
11 129 S.Ct. 1937, 1949-50 (2009) (citing Twombly, 550 U.S. at 555).

12 When granting a motion to dismiss, the court is generally  
13 required to grant the plaintiff leave to amend, even if no request  
14 to amend the pleading was made, unless amendment would be futile.  
15 Cook, Perkiss & Liehe, Inc. v. N. Cal. Collection Serv. Inc., 911  
16 F.2d 242, 246-47 (9th Cir. 1990). In determining whether amendment  
17 would be futile, the court examines whether the complaint could be  
18 amended to cure the defect requiring dismissal "without  
19 contradicting any of the allegations of [the] original complaint."  
20 Reddy v. Litton Indus., Inc., 912 F.2d 291, 296 (9th Cir. 1990).  
21 Leave to amend should be liberally granted, but an amended  
22 complaint cannot allege facts inconsistent with the challenged  
23 pleading. Id. at 296-97.

#### 24 DISCUSSION

##### 25 I. Pleading Standards

26 The parties disagree as to whether federal or state procedural  
27 law applies to this motion. Plaintiffs argue that, because the  
28 complaint was filed in state court, California's pleading rules

1 govern. This is not correct.

2 A Rule 12(b)(6) motion considers the substantive sufficiency  
3 of the pleadings as if the action had never been in state court.  
4 See Granny Goose Foods, Inc. v. Brotherhood of Teamsters & Auto  
5 Truck Drivers, Local No. 70 of Alameda County, 415 U.S. 423, 437  
6 (1974) ("[O]nce a case has been removed to federal court, it is  
7 settled that federal rather than state law governs the future  
8 course of proceedings, notwithstanding state court orders issued  
9 prior to removal."). Further, Federal Rule of Civil Procedure  
10 81(c) provides, "These rules apply to a civil action after it is  
11 removed from state court." This action has now been removed;  
12 therefore, federal law, not state law, governs the specificity that  
13 Plaintiffs must plead in order to survive a 12(b)(6) motion. Lopez  
14 v. GMAC Mortgage Corp., No. C 07-3911 CW, 2007 WL 3232448 at \*4  
15 (N.D. Cal.) ("In a case removed to federal court, the pleading  
16 requirements for a claim of fraud are analyzed under Federal Rule  
17 of Civil Procedure's 9(b).").

18 I. Off-Label Use of Humira Allegations

19 Abbott Labs argues that all causes of action against it should  
20 be dismissed because Plaintiffs did not allege that it promoted  
21 off-label use of Humera. Although the adequacy of Plaintiffs'  
22 allegations will be discussed below, the Court concludes that  
23 Plaintiffs have, at least in a general fashion, alleged that Abbott  
24 Labs promoted the off-label use of Humera. For instance, paragraph  
25 fifty-seven of Plaintiffs' complaint alleges that Humira's use in  
26 combination with Remicade and mercaptopurine in the treatment of  
27 autoimmune disorders, which "was not approved by the FDA," was  
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1 known to and promoted by Defendants.<sup>4</sup> Compl. ¶ 57. Therefore,  
2 this argument of Abbott Labs fails.

### 3 II. Learned Intermediary Doctrine

4 Abbott Labs also argues that all claims against it should be  
5 dismissed under the "learned intermediary" doctrine because "the  
6 FDA-approved labels for Humira specifically warned against the harm  
7 alleged here: the risk of lymphoma, particularly when Humira is  
8 used concomitantly with other immunosuppressive drugs." Motion at  
9 12. The learned intermediary doctrine provides that a drug  
10 manufacturer's duty to warn "runs to the physician, not to the  
11 patient." Carlin v. Superior Court, 13 Cal. 4th 1104, 1116 (1996).  
12 However, this rule does not absolve manufacturers of a duty to  
13 provide physicians with adequate warnings about drugs such that  
14 physicians can adequately inform their patients. Id. at 1108.  
15 Although Abbott Labs claims that its warnings were adequate, the  
16 Court cannot make such a determination in this case on a motion to  
17 dismiss. Plaintiffs do not disagree that Abbott Labs provided a  
18 warning to physicians, but they dispute whether the warning  
19 adequately conveyed to physicians the known or knowable risks of  
20 Humira. At the pleading stage, Abbott Labs has not proved that the  
21 "learned intermediary" doctrine bars all of Plaintiffs' claims.  
22 Thus, the Court denies Abbott Labs' motion to dismiss Plaintiffs'  
23 complaint based on this defense.

### 24 III. Fraud, Negligent Misrepresentation and Business and 25 Professions Code Section 17200

26 Plaintiffs' first, third and ninth causes of action are for

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27 <sup>4</sup>Of course if it were later to appear that Plaintiffs had no  
28 good faith reason to believe that Abbott Labs promoted the off-  
label use of Humira, Rule 11 sanctions would apply.

1 fraud, negligent misrepresentation and violation of Business and  
2 Professions Code Section 17200 respectively. Because these causes  
3 of action are all grounded in allegations of fraud, the Court will  
4 discuss them together.

5 Under California law, "[t]he elements of fraud, which gives  
6 rise to the tort action for deceit, are (a) misrepresentation  
7 (false representation, concealment, or nondisclosure);  
8 (b) knowledge of falsity (or 'scienter'); (c) intent to defraud,  
9 i.e., to induce reliance; (d) justifiable reliance; and  
10 (e) resulting damage." Small v. Fritz Cos., Inc., 30 Cal. 4th 167,  
11 173 (2003) (quoting Lazar v. Superior Court, 12 Cal. 4th 631, 638  
12 (1996)). A claim for negligent misrepresentation does not require  
13 scienter or intent to defraud; rather, to establish fraud through  
14 non-disclosure or concealment of facts, it is necessary to show  
15 that the defendant "was under a legal duty to disclose them."  
16 Lingsch v. Savage, 213 Cal. App. 2d 729, 735 (1963); Buckland v.  
17 Threshold Enterprises, Ltd., 155 Cal. App. 4th 798 (2007).<sup>5</sup>

18 "In all averments of fraud or mistake, the circumstances  
19 constituting fraud or mistake shall be stated with particularity."  
20 Fed. R. Civ. Proc. 9(b). The allegations must be "specific enough  
21 to give defendants notice of the particular misconduct which is  
22 alleged to constitute the fraud charged so that they can defend  
23 against the charge and not just deny that they have done anything

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24  
25 <sup>5</sup>Most district courts within California have held that a  
26 negligent misrepresentation claim is subject to the heightened  
27 pleading requirements of Rule 9(b). Deitz v. Comcast Corp., 2006  
28 WL 3782902 (N.D. Cal.); Neilson v. Union Bank of California, N.A.,  
290 F. Supp. 2d 1101, 1141 (C.D. Cal. 2003) (stating that the  
elements of a cause of action for negligent misrepresentation are  
the same as those of a claim for fraud, with the exception that the  
defendant need not actually know the representation is false).

wrong." Semegen v. Weidner, 780 F.2d 727, 731 (9th Cir. 1985). Statements of the time, place and nature of the alleged fraudulent activities are sufficient, id. at 735, provided the plaintiff sets forth "what is false or misleading about a statement, and why it is false." In re GlenFed, Inc., Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994). Scienter may be averred generally, simply by saying that it existed. Id. at 1547; see Fed. R. Civ. Proc. 9(b) ("Malice, intent, knowledge, and other condition of mind of a person may be averred generally"). Allegations of fraud based on information and belief usually do not satisfy the particularity requirements of Rule 9(b); however, as to matters peculiarly within the opposing party's knowledge, allegations based on information and belief may satisfy Rule 9(b) if they also state the facts upon which the belief is founded. Wool v. Tandem Computers, Inc., 818 F.2d 1433, 1439 (9th Cir. 1987).

Here, Plaintiffs' fraud claims do not meet Rule 9(b)'s requirements. Plaintiffs have not identified which Defendant is alleged to have made the misrepresentations or omissions, let alone the specific persons who made the fraudulent statements. Swartz v. KPMG LLP, 476 F.3d 756, 764-65 (9th Cir. 2007) ("Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant . . . and inform each defendant separately of the allegations surrounding his alleged participation in fraud.") (internal quotations, brackets, and citation omitted).

Further, Plaintiffs have not plead facts describing what is false or misleading about any of Abbott Lab's statements. Plaintiffs generally allege that Defendants' "representations



1 regarding the safety and efficacy of their drug products when used  
2 either singly or in combination were in fact false and inaccurate"  
3 because "the use of their products either singly or in combination  
4 . . . was directly associated with and/or known to cause cancers,  
5 including and particularly hepatosplenic T-cell lymphoma." Compl.  
6 ¶ 73. Allegations such as these do not explain how any statement  
7 or omission was false. Therefore, the Court grants Abbott Labs'  
8 motion to dismiss these causes of action.

9 IV. Negligence, Strict Liability and Wrongful Death

10 Plaintiffs' claims for negligence, negligence per se, strict  
11 liability and wrongful death also fail to state a claim.<sup>6</sup> Although  
12 not governed by the same heightened pleading standards as fraud  
13 claims, these allegations fail to specify any tortious conduct by  
14 Abbott Labs. Plaintiffs simply recite the elements of each cause  
15 of action and repeat the same failure-to-warn allegations.  
16 Plaintiffs fail to allege how Abbott Labs' warnings about Humira  
17 were inadequate, how it was negligent in failing to satisfy any  
18 other duty of care alleged or how it violated any specific  
19 California consumer protection law that would serve as the basis of  
20 Plaintiffs' negligence per se claim. Plaintiffs' "[t]hreadbare  
21 recitals of the elements of a cause of action, supported by mere  
22 conclusory statements," are insufficient to state a claim. Iqbal,  
23 129 S. Ct. at 1949-50.

24 Further, Plaintiffs' opposition does not even address these  
25 causes of action, choosing instead to rely on the argument that  
26 Abbott Labs failed to "challenge the sufficiency of the pleadings  
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28 <sup>6</sup>These claims comprise counts two, four, five, six and ten.

1 under California law." Opposition at 27. As noted above, federal  
2 pleading standards control this motion and Plaintiffs' failure to  
3 respond to Abbott Labs' arguments regarding these causes of action  
4 leaves the Court with little option but to grant Abbott Labs'  
5 motion on these claims.

6 V. Breach of Express and Implied Warranties

7 Plaintiffs' seventh and eighth causes of action are for breach  
8 of express and implied warranty respectively. Abbott Labs argues  
9 that these claims fail because it is not in privity with  
10 Plaintiffs. However, California recognizes an exception to the  
11 privity requirement in breach of warranty claims pertaining to food  
12 or drug products. Gottsdanker v. Cutter Labs., 182 Cal. App. 2d  
13 602 (1960). Abbott Labs asks the Court to ignore the rule in  
14 Gottsdanker because it has not been addressed by the California  
15 Supreme Court. The Court will not do so. Abbott Labs has not  
16 presented any California authority to suggest that this rule is no  
17 longer valid or that the California Supreme Court would rule as  
18 such.

19 However, for a different reason, the Court dismisses  
20 Plaintiffs' warranty claims. Simply stated, Plaintiffs'  
21 allegations fail to state a claim under Rule 8(a). Plaintiffs  
22 merely allege that Defendants expressly and impliedly "warranted"  
23 that the products were "safe, effective, fit and proper for their  
24 intended use," and that the products "were not safe and were unfit"  
25 for their intended uses." Compl. ¶¶ 120-21, 124, 126. Plaintiffs  
26 have not alleged the contents of any specific warranty or the  
27 breach thereof. Plaintiffs must allege more than just the elements  
28 of a warranty cause of action to survive a motion to dismiss.

## CONCLUSION

For the foregoing reasons, the Court grants Abbott Labs' motion to dismiss. Docket No. 39. Plaintiffs may amend their complaint to cure the deficiencies outlined above. Plaintiffs may file an amended complaint within twenty-one days from the date of this order. If Plaintiffs do so, Abbott Labs may file a motion to dismiss three weeks thereafter, with Plaintiffs' opposition due two weeks following and Abbott Labs' reply due one week after that. Abbott Labs' motion, if one is filed, shall be taken under submission on the papers. Defendants who have already answered need not file another answer. A case management conference shall be held on April 20, 2010 at 2:00 p.m.

IT IS SO ORDERED.

Dated: 01/20/10



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CLAUDIA WILKEN  
United States District Judge